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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Francesco Santangelo

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

04/16/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	Application No.	Applicant(s) SANTANGELO, FRANCESCO	
	Examiner Phyllis G. Spivack	Art Unit 1614	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 31 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): the rejection of record under 35 U.S.C. 112, first paragraph.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-4 and 10.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

/Phyllis G. Spivack/  
Primary Examiner, Art Unit 1614

Continuation of 3. NOTE: There is no clear support in the specification for the proposed term "inhibiting" in claim 1 .

Continuation of 11. does NOT place the application in condition for allowance because: In the last Office Action claims 1-4 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al., U.S. Patent 4,794,124, in view of Dall'Aglio et al., WO 0053176.

Yamamoto teaches the oral administration of cysteine in amounts of 10-5000 mg to treat diabetic nephropathy, i.e., any pathology of the kidney. The most common cause of end-stage renal disease is diabetic nephropathy. See column 1, lines 13-20, where Yamamoto teaches the requirement of hemodialysis for diabetic patients in whom nephropathy has progressed to renal failure. Sela et al., Kidney International, teaches oxidative stress is associated with hemodialysis. Dall'Aglio teaches the administration of cysteine as a detoxicating agent to treat oxidative stresses.

Applicant argues Yamamoto does not administer a specific dose at specific times associated with a particular event, namely hemodialysis, at a particular time to treat an acute condition brought about by hemodialysis. Applicant urges Yamamoto talks generally about the use of cysteine to treat diabetic complications, but only cataract treatment is described. Applicant argues Dall'Aglio requires combination therapy to achieve the desired relief of oxidative stress.

Applicant's arguments have been given careful consideration but are not found persuasive. The rejection of claims 1-4 and 10 under 35 U.S.C. 103 is maintained for the reasons of record. It is noted the present claims are not limited to an "acute condition" in the sense of a sudden onset. Although instant claim 10 requires the administration of the active agent from within a recited range, that range is entirely encompassed by Yamamoto's teaching. Other than the recitation in claim 4, of administration "before and/or after hemodialysis treatment," - a parameter which is readily ascertainable by one skilled in the art through no more than routine experimentation - no "specific times associated with a particular event" are claimed. Instead, a rather general recitation of "treating oxidative stress resulting from hemodialysis" is stated. In view of the open language of claims 1 and 10, any number of additional active agents may be administered along with cystine, cysteine or mixtures thereof.

In view of the combined teachings of the prior art, one skilled in the nephrology art would have been motivated to administer cysteine to treat the oxidative stress resulting from hemodialysis with a reasonable expectation of success. A clear association between oxidative stress and hemodialysis is taught by Sela. Dell'Aglio teaches the administration of cysteine to treat oxidative stress. According to Yamamoto, diabetic nephropathy commonly advances to renal failure, which requires hemodialysis. Cysteine in amounts of 10-5000 mg is effective in the treatment of nephropathy.